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An assessment of the cost-utility of therapy for psoriasis

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Objective: Recently a number of new therapies have been introduced to treat psoriasis, but concerns have been expressed about their high cost. The purpose of this study was to determine whether most psoriasis treatments lie within the accepted range of cost-utility.

Methodology: 32 patients with moderate to severe psoriasis were administered the Euro-Qol 5 Dimension (EQ-5D) survey to calculate their health state utility. Economic modeling was performed with a range of therapeutic costs applying the calculated utility score. Paired t-tests were used to calculate significance.

Results: At the conclusion of 2 weeks of therapy, the mean psoriasis area and severity index (PASI) improved 35% to 7.2 ($p < 0.001$). The mean health state utility score on the EQ-5D improved 11.5% from 77.7 units before therapy to 86.7 units after therapy ($p = 0.007$).

Conclusion: A therapy that achieves at least a PASI 35 would be considered cost-effective by conventional standards if it does not exceed \$33 600 in cost.

Keywords: psoriasis, cost-utility analysis, health economics

Introduction

Despite substantial efforts and policy changes during the past two decades, health care costs continue to rise (Russell 1994). It is estimated that by 2011, healthcare spending will exceed 15% of gross US domestic product (CMS 2004). The dramatic rise in healthcare expenditure has been fueled by the development of novel therapeutics. In psoriasis, for instance, recent years have seen the approval of 3 biologic response modifiers to treat the disease, all costing about US\$10–20 000 per year for medication alone, substantially increasing the direct cost of care from prior estimates (Javitz et al 2002; Leonardi 2004; Rich 2004). Indeed, this can be compared with the therapeutic cost of methotrexate, with all of its concomitant side effects, of approximately US\$1000/year (Opmeer et al 2004). Even prior to the development of biologic therapy, the annual cost of treating psoriasis had been estimated at between US\$1.6 billion and US\$3.2 billion (NPF 2006).

Utility is the preference of an individual for a particular health state or treatment outcome. Utilities for a given health state have been measured using different populations, including the general public, patients who have experienced the disease state, and other surrogate respondents. Cost utility analysis (CUA) is a specific type of cost-effectiveness analysis (CEA) using quality-adjusted life years as the effectiveness endpoint. The cost-utility ratio is the incremental cost of an intervention to achieve one quality adjusted life year, compared with an alternative intervention (Guyatt et al 1993; Gold 1996).

The Euro-Qol 5 Dimension (EQ-5D) is a standardized generic instrument developed for describing and valuing health states (EuroQol Group 1990). The EQ-5D was developed for use in population health surveys or in conjunction with a condition-targeted instrument for assessment of outcomes related to specific health conditions or their treatment (Kind 1996). It specifically refers to health status at the

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time of questioning. The EQ-5D produces three types of data for each respondent: (1) a description of the extent of the problem along five health dimensions; (2) a population-weighted health index; and (3) a self-rated assessment of health status using a visual analog scale (VAS) (Kind 1996).

The utility measurement records a patient's health state along five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each dimension has three levels reflecting no problem, some problem, and extreme problem. Respondents are asked to indicate one of the three levels along each of the five dimensions. This classifies respondents into 1 of 125 distinct health states (Dolan 1997). The applied valuation, to assign a utility to each health state, was developed in the UK using the time trade-off method (Dolan 1997). Utility measures, derived from economic and decision theory, reflect the preferences of patients for treatment process and outcome, thus indicating the value of that health status to the patient.

Conventionally, an affordable healthcare intervention has been defined as that which produces a single unit of health state utility, the quality adjusted life year (QALY), for between US\$50 000 and US\$100 000 (Ubel et al 2003). An intervention that cures a patient of a health condition with a quality of life halfway between perfect health and death yields 0.5 QALYs per year. A return to perfect health yields one QALY per year (Gold 1996).

The purpose of this study is to provide a preliminary estimate of the cost-utility of therapy for psoriasis.

Methods

Thirty-two patients with moderate to severe psoriasis were administered the EQ-5D survey to calculate their

health state utility during a randomized controlled trial evaluating the efficacy of a topical therapy in different formulations that was approved by the Stanford Panel on Human Subjects. The methodology of this study has been previously reported (Bergstrom et al 2003). In brief, the study was a single-blind design in which 32 patients were randomized into 2 groups and applied either clobetasol foam 0.05% to the skin and scalp or combination clobetasol cream 0.05% to the skin and clobetasol solution 0.05% to the scalp. The treatment period was 14 days and there were no significant differences in the two randomized groups.

Established values for health utility were taken from the published literature, including the value of no chronic conditions (EuroQol Group 1990). The utility score was calculated as the improvement in utility from the use of a topical therapy that achieved a 35% improvement in psoriasis area and severity index (PASI), divided by the difference between the utility value of psoriasis with a mean baseline PASI of 11 prior to treatment and the utility value of having no chronic diseases. Economic modeling was performed with a range of therapeutic costs applying the calculated utility score. Paired t-tests were used to calculate significance.

Results

The mean PASI at entry was 11.1 (Table 1). The mean health state utility score on the EQ-5D for psoriasis was 77.7 units. At the conclusion of 2 weeks of therapy, the mean PASI was 7.2, a 35.0% improvement ($p < 0.001$). The resulting utility score on the EQ-5D, following therapy, was 86.7 units, an 11.5% improvement ($p = 0.007$).

Table 1 Analysis

	<u>Before</u>	<u>After</u>	<u>Change (%)</u>	<u>P value</u>
EQ5D	0.78	0.87	11.5	0.007
PASI	11.08	7.20	-35.0	<0.001
SAPASI	15.73	11.61	-26.2	0.04
DLQI	9.39	5.61	-40.2	<0.001
VAS	67.65	73.16	8.2	0.001
BSA	12.44	9.90	-20.4	<0.001

Abbreviations: BSA, body surface area; DLQI, Dermatology Life Quality Index; EQ5D, European QoL 5 Dimension survey; PASI, psoriasis area and severity index; SAPASI, self-assessed psoriasis area and severity index; VAS, visual analog scale.

During the 2 week study, total body surface improved 20.4% ($p<0.001$). Quality of life as measured by the dermatology life quality index (DLQI) and the EQ-5D VAS improved 40.2% and 8.2% respectively ($p<0.001$). The patient's perception of disease severity, as measured by the self-assessed PASI (SAPASI), improved 26.2% ($p=0.04$).

The mean established value for individuals with no chronic conditions is 91 units, 13.3 units more desirable than having psoriasis with a PASI of 11.1. The 11.5% improvement in psoriasis severity therefore corresponds to a QALY score of 0.67. In other words, a therapy for psoriasis that yields a 35% improvement in PASI results in an incremental gain of 0.67 QALYs, two-thirds the value of having no chronic conditions. Table 2 illustrates the application of the calculated utility score to a range of therapeutic costs, generating the cost-utility value of proposed therapies. A therapy that achieves a 35% improvement in PASI is considered cost-effective, defined as a CUA less than US\$50 000/QALY if it does not exceed US\$33 600 in cost. Moreover, therapy for psoriasis that attains a PASI 35 has a more favorable cost-utility ratio than other more commonly accepted healthcare interventions including annual retinopathy screening for low risk patients with diabetes (Table 3) (Ubel et al 2003).

Discussion

An affordable healthcare intervention is conventionally defined in the US as that which yields a value of US\$50 000/QALY (Gold 1996; Ubel et al 2003). Based on this

Table 2 Incremental cost-utility of a PASI 35 at different annual costs of therapy

Annual Cost of Therapy	CUA
\$ 6,000.00	\$ 8,925.08
\$ 12,000.00	\$ 17,850.16
\$ 18,000.00	\$ 26,775.24
\$ 24,000.00	\$ 35,700.33
\$ 30,000.00	\$ 44,625.41
\$ 34,000.00	\$ 50,575.46

Abbreviations: CUA, cost-utility analysis; PASI, psoriasis area and severity index.

Table 3 Comparisons across disease – Health State Utility (Ubel et al 2003)

Disease	Utility Score
CABG for coronary artery disease	0.84
Medical subgroup refusing CABG for Coronary Artery Disease	0.74
Psoriasis (PASI 35)	0.78
Medical management for Coronary Artery Disease	0.61

Abbreviations: CABG, coronary artery bypass graft; PASI, psoriasis area and severity index.

preliminary cost-utility analysis, therapy for psoriasis that achieves at least a PASI 35 and costs up to US\$34 000 annually, is comparably affordable with treatments for other medical conditions.

Importantly, a 35% reduction in PASI is a modest, although meaningful, reduction of the extent of psoriasis. Most new therapies have been judged on their ability to produce a PASI 75. These results from this study are therefore based on a degree of clearance that is clearly clinically relevant, but is significantly less than the improvement brought about by many systemic therapies. Of note, for most people with a PASI of 11, topical therapy is likely to be time-consuming and inconvenient – and might have negatively impacted the level of improvement observed during the two week treatment period compared with more convenient therapies.

The QALY score for the current study is derived after 2 weeks of therapy, which is the US Food and Drug Administration (FDA)-recommended duration of this treatment. Typically in clinical practice, after improvement is achieved, it is maintained with other topical medications. With adequate compliance we would expect this QALY score could be maintained over the course of a year of treatment and might possibly improve, implying that cost-effectiveness might increase over time.

This analysis is based upon the use of traditional methodologies for analyzing the cost-utility of any given treatment. There are several limitations to the application of this analysis to psoriasis. First, the methodology does not adjust for variations in the baseline utility scores at the beginning of the treatment. Second, the methodology is most rigorously applied to diseases in which a single treatment leads to persistent health effects such as a cancer treatment which brings remission. The translation into the analysis of utility of treating chronic conditions, especially chronic conditions which wax and wane, is complicated by difficulty in determining how subjects will measure their utility over time.

Nonetheless, it is essential to continue to evaluate the health-related quality of life experienced by patients with psoriasis and other skin diseases, because despite the assumption that these are problems of a strictly cosmetic nature, they demonstrate significant impairment on health state utility (Jenner et al 2002; Weiss et al 2002, 2003). Moreover, the benefits achieved from therapy compare favorably with therapies that are routinely covered by third party payers. Therefore, the next step is to assess prospectively the incremental benefit in health state utility of psoriatic therapies by incorporating the EQ-5D into large randomized controlled studies including phase III and IV study protocols.

Today, more than ever before, dermatologists have been provided the tools to improve significantly the physical stigmata of psoriasis that affects its sufferers. These results demonstrate that the value of medicines for treating psoriasis provide utilities comparable with that of other therapies in other areas of medicine.

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